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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,196	12/04/2003	Orapin P. Rubino	1289-002US1	7287
47888 7590 09/14/2010 HEDMAN & COSTIGAN, P.C. 1230 AVENUE OF THE AMERICAS 7th floor NEW YORK, NY 10020				
EXAMINER HUANG, GIGI GEORGIANA				
ART UNIT		PAPER NUMBER		
1617				
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09/14/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/728,196

**Applicant(s)**

RUBINO ET AL.

**Examiner**

GIGI HUANG

**Art Unit**

1617

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 and 18-34 is/are pending in the application.
- 4a) Of the above claim(s) 15, 16 and 18-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 30-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of Application***

1. The response filed June 21, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:
  - a. Claims 1, 13-14 have been amended.
  - b. Claim 17 and the 18(second) have been cancelled.
2. Claims 1-16, 18-34 are pending in the case.
3. Claims 1-14, 30-34 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.
6. New grounds of rejection are set forth in the current office action as a result of amendment.
7. It is noted that the withdrawn claims do not have claim identifiers indicating the withdrawn status, correction is suggested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 recites the limitation "swellable polymer" in claim 8. There is insufficient antecedent basis for this limitation in the claim. It is also unclear

where the swellable polymer is structurally placed. For purposes of prosecution, any location in the pellet applies.

9. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites the limitation "release rate controlling polymers" in claim 11. There is insufficient antecedent basis for this limitation in the claim. It is also unclear where the release rate controlling polymer is structurally placed. For purposes of prosecution, any location in the pellet applies.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Samejima et al. (U.S. Pat. 4963365).

Samejima et al. teaches a controlled release dosage form with a core containing an medicament and excipients including binders and diluents (inner zone), an inner coating with ethylcellulose (release rate controlling polymer) and a hydrophobic substance (e.g. talc, alkali earth metal stearates, calcium carbonate, colloidal silica), may have a middle coating layer with ethylcellulose (release rate controlling polymer) or ethylcellulose and a water soluble substance, and an outer layer. The granules can also be placed in hard gelatin capsules which are exemplified. Example 1 has a core of

diltiazem (69-.7%) with polyvinylpyrrolidone (7.0%, a swellable polymer, binder) and lubricant/anti-aggregating-talc (5.8%), that is coated with an inner coating layer containing ethylcellulose and talc, middle layer (ethylcellulose, sucrose), outer layer, and surface coating layer (all outer zone). Similar examples are present in Example 2 and 14-24, including granules in hard capsules and a layer with ethylcellulose (non-swellable polymer) and polyethylene glycol (Macrogol-swellable polymer) (Abstract, Col. 1 line 20-68, Col.2 line 30-60, Col. 3 line 9-21 line 40-Col. 4 line 5, Col. 4 line 32-44, Example 1-2, 14-24).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

12. Claims 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Faour et al. (U.S. Pat. 6004582).

Faour et al. teaches a dosage form comprising an active in a core with excipients in the claimed ranges, with polymer and powdered coating comprising the polymers and the powders of the claims with actives including hydroxypropylmethylcellulose (HPMC, swellable polymer) and ammonium polymethacrylate (methacrylic acid copolymer, release rate controlling polymer, e.g. example 3). Faour also teaches various polymers for the polymer coat (3) including HPMC, cellulose acetate phthalate, hydroxypropylmethylcellulose acetate succinate (Col. 7 line 15-41) (see full document, specifically Examples 1-8 and claims).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

***Claim Rejections - 35 USC § 103***

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samejima et al. (U.S. Pat. 4963365) as applied above.

The teachings of Samejima are addressed above. Samejima does not expressly teach an example with the swellable polymers HPMC, hydroxypropylcellulose, hydroxyethylcellulose, and carboxypolymethylene (Carbopol, carbomer, polyacrylic), but does teach the incorporation of these polymers (Col.1 line 58-63) and that they are functional equivalents with polyvinyl pyrrolidone (PVP); wherein it would be obvious to one of skill in the art to substitute a functionally equivalent polymer like HPMC for PVP as it is desirable for manufacturers to have functionally choices to substitute the binder when motivated by pricing, availability, or desired properties of the binder used to produce the final product.

***Response to Arguments***

14. Claims 1-10, 12 and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Samejima et al. (U.S. Pat. 4963365).

Applicant's arguments filed 5/24/2010 and 6/21/2010 have been fully considered but they are not persuasive. Applicant's arguments center on the method of making amendment into the composition claims where the method of making has been restricted from the examination and a product by process recitation is treated as a product claim wherein the product is the limitation to be met. Samejima fulfills the structural components of the claims.

Accordingly, the rejection is maintained.

15. Claims 1-12 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Faour et al. (U.S. Pat. 6004582).

Applicant's arguments filed 5/24/2010 and 6/21/2010 have been fully considered but they are not persuasive. Applicant's arguments center on the method of making amendment into the composition claims where the method of making has been restricted from the examination and a product by process recitation is treated as a product claim wherein the product is the limitation to be met. Samejima fulfills the structural components of the claims.

Accordingly, the rejection is maintained.

16. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samejima et al. (U.S. Pat. 4963365) as applied to claim 1-5, 7-12 and 30-34 above, in view of Kjornaes et al. (U.S. Pat 4716041).

Applicant's arguments filed 5/24/2010 and 6/21/2010 have been fully considered but they are not persuasive. Applicant's arguments center on the method of making amendment into the composition claims where the method of making has been restricted from the examination and a product by process recitation is treated as a product claim wherein the product is the limitation to be met. Samejima fulfills the structural components of the claims.

Accordingly, the rejection is maintained.

17. Claims 1-14 and 30-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-17 and 31-34 of copending Application No. 11/596090.

There are no arguments or terminal disclaimer.

Accordingly, the rejection is maintained.

***Conclusion***

18. Claims 1-14 and 30-34 are rejected.
19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, FEREDOUN SAJJADI can be reached on 571-272-3311. The fax phone



number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/  
Examiner, Art Unit 1617  
/Zohreh A Fay/  
Primary Examiner, Art Unit 1627